



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D433563; **FILE SYMBOL No.:** 7969-GIE (screen); **PRODUCT NAME:** Selontra Rodent Bait; **DECISION No.:** 516184; **PC Code(s):** 202901; **ACTION CODE:** R334; **FOOD Use:** No

**DATE OUT:** August 5, 2016

**SUBJECT:** 45/90 day screen results for end use product "Selontra Rodent Bait [(BAS 410 06 I)]"

**FROM:** Shyam Mathur, Chemistry Team Leader, CITAB / RD (7505P)

**TO:** William Jacobs / Venus Eagle, RM 01; I-V Branch 3 / RD (7505P)

**Company Name:** BASF Corporation

**Active Ingredient(s):** Cholecalciferol (0.075%) [unregistered source]

**MRID No(s):** 49667505, 49667507, 49667516, , 49667521, 49667522

**CONCLUSION:**

**Deficiencies:** No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

All group A & Group B data submitted for the **unregistered Cholecalciferol technical product**  
With MRID Nos.: 49667501 to 49667504

**Group A:** All required data submitted,

**Group B:** All required data submitted.

**CSF:** Proposed Basic CSF and alternate CSF's #1 to #4 (all dated 03-30-2016) submitted

**DRAFT PRODUCT LABEL:** Submitted

Note to PM: Since the product was found to be incompatible with oxidizing agents, the registrant is recommended to add the following statement under Physical-Chemical Hazards on the product label:

"Do not mix or allow coming in contact with oxidizing agent. Hazardous Chemical reaction may occur"

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report the corrected deficiencies in response to 10 day letter. The corrected deficiencies will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



**FEE**

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**DP BARCODE No.:** D433563; **FILE SYMBOL No.:** 7969-GIE; **PRODUCT NAME:** Selontra Rodent Bait; **DECISION No.:** 516184; **PC Code(s):** 202901; **ACTION CODE:** R334; **FOOD Use:** No; **COMPANY NAME:** BASF Corporation

**DATE OUT:** January 30, 2017

**SUBJECT:** End Use Product Chemistry Review  
Product Name: Selontra Rodent Bait (with Un-registered active ingredient)

**FROM:** Shyam Mathur,  
Product Chemistry Team Leader  
CITAB/RD (7505P)

*S. Mathur*  
*01-30-17*  
*JCH*

**TO:** William Jacobs / Venus Eagle, RM 01  
I-V Branch 3 / RD (7505P)

**INTRODUCTION:**

The registrant BASF Corporation, has submitted an application for the registration of a new end use product Selontra Rodent Bait (BAS 410 06 I) a ready-to-use soft block rodent bait (RB) enrobed in a perforated flavor-permeable wrapper for the control of house mice, Norway Rats and roof rats. The product Selontra Rodent Bait contains unregistered active ingredient cholecalciferol for which the registrant submitted product chemistry data under MRID Nos's 49667501 to -04. The registrant has submitted a basic CSF and four alternate CSF's #1 to #4 (all dated 30 March 2016) and the supporting product chemistry data with MRID No's: 49667505, 49667507, 49667516, 49667521 & 49667522.

CITAB has been asked to review the proposed basic & alternate CSF's and the supporting group A & B product chemistry data submitted for the proposed end use product along with the product chemistry data for the unregistered source of the AI

**Note:** The product chemistry report for the unregistered cholecalciferol TGAI/MUP is given on Page # 7 of this report.

DP BARCODE No.: D433, FILE SYMBOL No.: 7969-GIE; PRODUCE NAME: Selontra  
Rodent Bait; DECISION No.: 516184; PC Code(s): 202901; ACTION CODE: R334; FOOD Use:  
No; COMPANY NAME: BASF Corporation

**End-use product Report**

**SUMMARY OF FINDINGS:**

1. Name of Active Ingredient(s): Cholecalciferol (0.075%)

2. Has the registrant claimed substantial similarity to a registered product?

☐ Yes; ☒ No; ☐ NA; if yes give the registration number of the cited product.

EPA Reg. No:

3. All of the source materials of the active ingredient are derived from registered sources

☐ Yes; ☒ No

**Note:** The registrant has used unregistered source of the active ingredient cholecalciferol  
For the product chemistry data has been submitted.

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed  
Label uses.

5. Confidential Statement of Formula(s):

☒ Basic - Dated: 03-30-16; Re-submitted - Dated:

☒ Alternate CSF's #1 to #4 - All Dated: 03-30-2016; Re-submitted - Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☐ NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product  
Product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other  
Ingredients)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;  
Soluble arsenic: ☐ Yes ☒ NA  
Isomeric ratios: ☐ Yes ☒ NA;  
Acid Equivalent: ☐ Yes ☒ NA; acid equivalent =

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA  
Methanol at > 4%: ☐ Yes ☒ No ☐ NA  
Sodium nitrate/Sodium nitrite ☐ Yes ☒ No ☐

DP BARCODE No.: D433, FILE SYMBOL No.: 7969-GIE; PRODUCE NAME: Selontra  
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No; COMPANY NAME: BASF Corporation

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

DP BARCODE No.: D433; FILE SYMBOL No.: 7969-GIE; PRODU. NAME: Selontra  
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 No; COMPANY NAME: BASF Corporation

7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the below.  
 Table:

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	49667516
830.1600	Description of materials used to produce the product		X		A	49667516
830.1650	Description of formulation process		X		A	49667516
830.1670	Discussion on the formation of impurities		X		A	49667516
830.1700	Preliminary analysis		X		A	49667516
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Basic CSF dated 03-30-2016
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	49667522

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable

DP BARCODE No.: D433, FILE SYMBOL No.: 7969-GIE; PRODUCT NAME: Selontra  
 Rodent Bait; DECISION No.: 516184; PC Code(s): 202901; ACTION CODE: R334; FOOD Use:  
 No; COMPANY NAME: BASF Corporation

8. Group B: Product chemistry data submitted

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Solid	A	49667505
830.6315	Flammability	>100°C	A	49667521
830.6316	Explosibility	Does not contain any explosive components	A	49667521
830.7000	pH	6.7 at 20°C (1% solution in water)	A	49667505
830.7300	Density (units)	1.333 g/cc (11.1 lbs/gal) at 20°C	A	49667505
830.7100	Viscosity	TS is a solid	NA	
830.6317	Accelerated Storage stability	TS was found to be stable for 2 weeks when stored in commercial containers at 54°C	A	49667505
830.6320	Accelerated Corrosion characteristics	No major changes in the appearance or integrity of commercial packaging was observed when stored at 54°C for 2 weeks. No significant weight loss of the container was seen. Some minor paneling was noted during the study.	A	49667505
830.6314	Oxidation/reduction	TS was found to be compatible with water, Fe powder, 10% ammonium phosphate solution and kerosene. Incompatible with 10% potassium permanganate	A	49667507

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable; L = In progress

DP BARCODE No.: D433; FILE SYMBOL No.: 7969-GIE; PRODU .JAME: Selontra  
Rodent Bait; DECISION No.: 516184; PC Code(s): 202901; ACTION CODE: R334; FOOD Use:  
No; COMPANY NAME: BASF Corporation

**CONCLUSIONS:**

CITAB has reviewed the product chemistry data submitted for the end-use product and has concluded that:

**A. Substantial similarity to the cited product (Reg. No. ) from Product chemistry view point**

- ☐ Similar
- ☐ Not similar, give reasons:
- ☐ Identical
- ☐ Not identical
- ☒ Not applicable

**B. Confidential Statement of formula**

- 1. Basic CSF (dated: 03-30-2016)
  - ☒ Acceptable
  - ☐ Not Acceptable:
  - ☐ Not Applicable
- 2. Alternate CSF's #1 to #4 (all dated: 03-30-2016 )
  - ☒ Acceptable
  - ☐ Not Acceptable:
  - ☐ Not Applicable

**C. Group A Product Chemistry Data**

- ☒ Acceptable
- ☐ Acceptable with the exception of the guideline:
- ☐ Not acceptable
- ☐ Not required
- ☐ Data cited

**D. Group B Product chemistry data**

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Acceptable with the exception of the guidelines
- ☐ Not required
- ☐ Data cited for the guidelines

**E. Product Label/Draft Label: Recommendations – Yes [X]; No [ ]**

Note to PM: Since the product was found to be incompatible with oxidizing agents, the registrant is recommended to add the following statement under Physical-Chemical Hazards on the product label:

"Do not mix or allow coming in contact with oxidizing agent. Hazardous Chemical reaction may occur"

DP BARCODE No.: D433; FILE SYMBOL No.: 7969-GIE; PRODU NAME: Selontra  
Rodent Bait; DECISION No.: 516184; PC Code(s): 202901; ACTION CODE: R334; FOOD Use:  
No; COMPANY NAME: BASF Corporation

**Report on un-registered Cholecalciferol**

**SUMMARY OF FINDINGS & CONCLUSIONS:**

CITAB has reviewed group A & group B product chemistry data submitted to support the  
unregistered active ingredient Cholecalciferol produced by [REDACTED]

and has concluded:

1. Group A product chemistry data submitted are acceptable.
2. The group B product chemistry data submitted are acceptable, except for the guideline  
830.700 (pH), 830.6313 (stability to metal & metal ions at room & elevated temperatures),  
830.6317 (storage stability) and 830.6320 (corrosion characteristics).
3. The registrant is recommended to submit the data on these guidelines. For storage & corrosion  
characteristics studies, the accelerated studies (2 weeks at 54°C) can be submitted.

*\*Product ingredient source information may be entitled to confidential treatment\**

*\*Claimed confidential by submitter\**

DP BARCODE No.: D4335 FILE SYMBOL No.: 7969-GIE; PRODU. NAME: Selontra  
Rodent Bait; DECISION No.: 516184; PC Code(s): 202901; ACTION CODE: R334; FOOD Use:  
No; COMPANY NAME: BASF Corporation

Product identity & Composition: (MRID No. 49667501)

Compendial/Common Name : Cholecalciferol

Chemical Name : (5Z, 7E)-(3S)-9,10-secocholesta-5,7,10(19)-trien-3 $\beta$ -ol.

Other Non-proprietary Name(s) : Calciol

Synonyms : Vitamin D3 crystalline

Chemical Abstracts Service registry Number : [67-97-0]

IUPAC Name : (1S)-3-[2-[(1R,7aR)-7a-methyl-1-[(2R)-6-methylheptan-2-yl]-2,3,3a,5,6,7-hexahydro-1H-inden-4-ylidene]ethylidene]-4-methylidenecyclohexan-1-ol

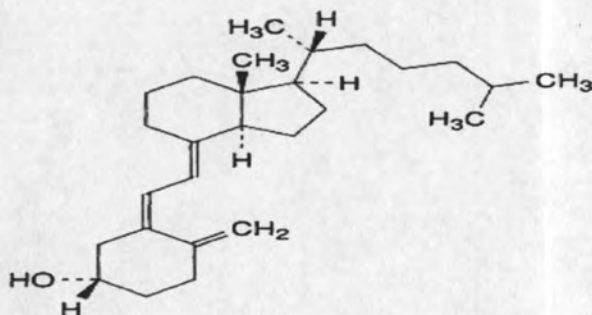
CAS chemical name : Cyclohexanol, 3-[(2E)-2-[(1R,3aS,7aR)-1-[(1R)-1,5-dimethylhexyl]octahydro-7a-methyl-4H-inden-4-ylidene]ethylidene]-4-methylene-, (1S,3Z)-

Molecular Formula : C<sub>27</sub>H<sub>44</sub>O

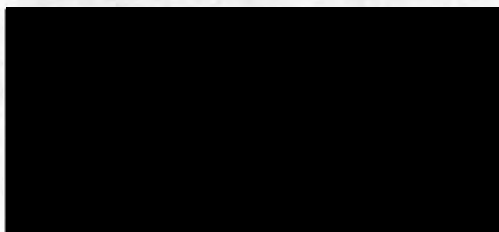
Molecular Weight : 384.64

Pesticidal Use : Rodenticide

Structural Formula :



Manufacturing site:



*\*Product ingredient source information may be entitled to confidential treatment\**

DP BARCODE No.: D433 FILE SYMBOL No.: 7969-GIE; PRODU JAME: Selontra  
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 No; COMPANY NAME: BASF Corporation

830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of MUP "Cholecalciferol technical"				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	49667502	A	White
830.6303	Physical state	49667502	A	Solid (crystalline powder)
830.6304	Odor	49667502	A	No odor detected
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	49667502	U	TS started decomposing at temperature of approximately at 150°C. No test was conducted for stability with metal & metal ions.
830.6314	Oxidation/reduction: chemical incompatibility	49667504	A	Structural examination of the AI indicated that cholecalciferol is not likely to possess oxidizing properties
830.6315	Flammability	49667502	A	Solid. Not highly flammable
830.6316	Explodability	49667503	A	Structural examination of the AI indicated that cholecalciferol is not likely to possess oxidizing properties
830.6317	storage stability		G	No data submitted
830.6319	Miscibility		NA	
830.6320	Corrosion characteristics		G	No data submitted
830.7000	pH		G	No data submitted
830.7050	UV/Visible absorption	49667502	A	See Table below under Note 1
830.7100	Viscosity		NA	
830.7200	Melting point	49667502	A	72.5 - 83°C (range)
830.7220	Boiling point	49667502	A	Onset of decomposition at 148°C
830.7300	Relative Density	49667502	A	1.02 @ 20°C
830.7370	Dissociation constants in water (DC)	49667501	A	AI contains no acidic or basic species likely to dissociate in the environmentally relevant pH range.
830.7550	Partition coefficient	49667502	A	Log <sub>10</sub> P <sub>o/w</sub> > 5.9 very soluble in organic solvents
830.7840	Water solubility	49667502	A	< 0.5 µg/L Very soluble in ethanol, chloroform, acetone & ether
830.7950	Vapor pressure	49667502	A	6 x 10 <sup>-5</sup> Pa at 25°C 4 x 10 <sup>-5</sup> Pa at 20°C
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required); W = waivers				

DP BARCODE No.: D433t FILE SYMBOL No.: 7969-GIE; PRODU NAME: Selontra  
Rodent Bait; DECISION No.: 516184; PC Code(s): 202901; ACTION CODE: R334; FOOD Use:  
No; COMPANY NAME: BASF Corporation

Solubility in organic solvents

The active ingredient cholecalciferol has solubility of >250 g/L in the following organic solvents:

n-heptane, xylene, 1, 2-dichloroethane, MeOH, acetone & ethyl acetate.

Note 1: 830.7050 (UV/VIS)

The following absorption wavelength maxima ( $\lambda_{\max}$ ) and molar absorption coefficients ( $\epsilon$ ) for Cholecalciferol were obtained:

Solvent	pH	$\lambda_{\max}$ (nm)	Absorbance	$\epsilon$ (dm <sup>3</sup> /mol/cm)
Purified water	7.0	215	1.0957	16400
		268	1.2292	18400
0.1M HCl	1.1	215	1.1169	16700
		268	1.2458	18600
0.1M NaOH	13.6	268	1.2305	18400

The absorbances for wavelengths below 220 nm for the basic spectrum were not reliable due to the cut-off of the solvent system.

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No; COMPANY NAME: BASF Corporation

CONFIDENTIAL APPENDIX

*\*Pages 13-21 Manufacturing process information may be entitled to confidential treatment\**